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Short communication

Migration limits for children's toys are nothing to play with

Ms Scientific Committee SCHER, Renate Krätke [1], Claire Beausoleil [1], Maria José Carroquino [1], Raquel Duarte-Davidson [1], Teresa Fernandes [1], Greet Schoeters [1]

European Commission, Directorate General for Health and Food Safety, L-2920 Luxembourg, Luxembourg

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ABSTRACT

The European Commission and its independent Scientific Committee on Health and Environmental Risks (SCHER) published their final Opinion on estimates of the amount of toy materials ingested by children. The SCHER was asked to review available data on the ingestion of the following three types of toy material by children, and evaluate whether the ingestion amounts which formed the basis for the migration limits of 19 elements in the Toy Safety Directive are still appropriate or whether they should be changed. In the final Opinion the SCHER considers the ingestion amounts mentioned above to be appropriate, and that these ingestion amounts should remain classified as daily amounts rather than weekly.

In its Final Opinion on estimates of the amount of toy materials ingested by children, published on 8 April 2016, the European Commission's independent Scientific Committee on Health and Environmental Risks (SCHER) recommends leaving the current amounts as daily instead of weekly estimates. A change was recently suggested in an Erratum to the report on chemicals in toys of the Dutch National Institute for Public Health and the Environment (RIVM)[2] published in 2008.

Ingestion is one of the most important ways by which children are exposed to elements from toy materials, particularly for children up to age 3 due to young children's tendency to place objects in their mouths or to frequently put their hands in their mouth while playing. The estimated amounts of ingested toy materials are the basis for the calculation of migration limits for elements in the Toy Safety Directive 2009/48/EC (TSD). The directive which entered into force in 2009 sets some of the highest safety standards for toys in the world, including migration limits for 19 elements in toys and toy components. The Directive applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.

The migration limits for certain elements pertain to various types of toy materials and are based on the assumption that a child would ingest 100 mg/d of dry, brittle, powder-like or pliable toy material, 400 mg/d of liquid or sticky toy material, and 8 mg/d of scraped-off toy material a day. The rational for the assumptions on amounts of toy material ingested by children as well as for the calculation of migration limits is provided in the RIVM report. However in January 2015, an 'Erratum' was added to the report, stating that the amounts of dry, brittle, powder-like or pliable toy material, and of liquid or sticky toy material might only be ingested weekly, rather than daily. Therefore, the derived acceptable limits were re-calculated by RIVM and proposed to be increased seven-fold.

In response to the Erratum published by the RIVM in 2015, the European Commission asked the SCHER to review data available on the ingestion of toy materials and to determine whether the limits set in the Directive were still appropriate. If the SCHER found that these limits were no longer appropriate, the Commission asked the Committee to suggest new amounts, clearly indicating the data on which they are based.

To address this task, the SCHER conducted a literature search to obtain new information on children's ingestion of toy materials. Various search strategies were used and recent information on child behaviour in relation to mouthing from reports and peer-

E-mail address: SANTE-C2-SCHEER@ec.europa.eu (Ms Scientific Committee SCHER).

[1] Member of the Scientific Committee on Health and Environmental Risks (SCHER).

[2] (RIVM report 320003001/2008).

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reviewed publications was considered.

The SCHER also consulted guidance documents for calculating indirect ingestion of non-food material by children. Additionally, a specific call for information on different toy materials ingested by children was published and made accessible to the general public on the Scientific Committees' website between 30 April 2015 and 12 June 2015.

Specifically, the SCHER focussed on two questions in order to produce its final Opinion:

(1) Is there new information available on the amount of toy materials that is ingested by children and
(2) Is there new information on the frequency that toy materials are ingested?

These enquiries and searches yielded no new reports or articles that directly addressed the question of the amount of toy materials ingested. Only one published study provided new data on mouthing behaviour related to toys in children aged 0–36 months and one meta-analysis was found on studies before 2009 on object-to-mouth frequency data (CEN, 2014; Xue et al., 2010). The amount of non-food materials ingested by children in general was derived from studies that were not even specifically based on toys, but on the ingestion of soil or dust by children. Soil was used as a surrogate to estimate ingestion of dry and powder-like toy material.

Both, frequency and duration of object-to-mouth activity are important parameters with regard to exposure assessment. Information on this behaviour allows for conclusions on possibilities for children to ingest toy materials. The new studies on mouthing behaviour support existing opinions and demonstrate that mouthing occurs frequently. There is a huge variability between children regarding mouthing frequency and duration, both of which depend greatly on the child's age and the type of toy. Children under 36 months mouthed toys on average 26 times/h, with 91 and 171 times/h as 95th and 99th percentiles, respectively. The studies also revealed differences between populations – babies in Spain, for example, tended to mouth toys significantly more often than babies in Germany, however, they mouthed the toys for much shorter periods than German babies. Children mouthed plastic and elastomeric toys much more often than other toys and surprisingly perhaps, toys that were not intended to be mouthed were mouthed almost as frequently as toys intended to be mouthed. It must be realised too, that children are likely to mouth *all* types of objects, not just toys of all sorts.

Regardless of the total exposure from all sources combined, it can be assumed that even if children do not play with a particular toy daily or even weekly, the contact with the three types of toy materials considered in this Opinion occurs frequently.

According to the European Chemicals Agency (ECHA) guidance on information requirements and chemical safety assessment (R.15: Consumer exposure estimation), daily, weekly and monthly consumer exposures can be seen as repeated exposures and assessed against a chronic health-based value. For products used infrequently, ECHA states that use frequency should not be used to average out exposure over a longer time period. According to the agency, exposure should be calculated for the actual duration of an event (event exposure), and then expressed as that concentration per day (ECHA, 2012).

The SCHER shares ECHA's views and would not advise recalculating migration limits on the basis of weekly rather than daily exposure. Given the lack of relevant new information pertaining to the amount of toy materials ingested by children and the frequency that toy materials are ingested, the SCHER is of the opinion that the current estimated ingestion amounts (100 mg/d of dry, brittle, powder-like or pliable, 400 mg/d of liquid or sticky and 8 mg/d of scraped-off toy material) are still appropriate.

The SCHER's recommendation takes into account the wide variety of toys, the differences in mouthing behaviour, the high frequency of mouthing toys by young children and the gaps in information. No new values are proposed.

SCHER members: Alena Bartonova, Claire Beausoleil, María José Carroquino, Pim De Voogt, Raquel Duarte-Davidson, Teresa Fernandes, Jadwiga Gzyl, Colin Janssen, Renate Krätke, Jan Linders, Greet Schoeters.

Transparency document

Transparency document related to this article can be found online at http://dx.doi.org/10.1016/j.yrtph.2016.07.014.

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